K061637

JUL 2 5 2006

510(k) Summary

1.0 SUBMITTER INFORMATION

1.1 Submitter:

SHIMADZU MEDICAL SYSTEMS

20101 South Vermont Ave. Torrance, CA 90502-1328

PH: 310-217-8855 FX: 310-217-8869

1.2 Contact:

Randal Walker

1.3 Date:

MAR. 17, 2006

2.0 DEVICE NAME

2.1 Proprietary Name:

SDU-2200Pro

2.2 Common Name:

Ultrasound Imaging System

2.3 Classification:

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550, Product Code 90-IYN Ultrasonic Pulsed Echo Imaging System FR # 892.1560, Product Code 90-IYO Diagnostic Ultrasound Transducer

FR # 892.1570, Product Code 90-ITX

2.4 Predicate Device:

Shimadzu SDU-2200 (K003514, Feb./12/01)

3.0 DEVICE DESCRIPTION

The SDU-2200Pro is a mobile diagnostic ultrasound system. This system has flat linear array, convex linear and sector probe with a frequency range of approximately 2 to 15 MHz. It has B mode, M mode, Pulsed Doppler mode, Continuous Doppler mode, Color mode, or in a combination of modes.

4.0 INTENDED USE

The SDU-2200Pro is intended for the following applications:

Fetal, Abdominal, Pediatric, Small Organs (Specify), Neonatal Cephalic, Adult Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculo-skeletal Superficial and Musculo-skeletal Conventional.

5.0 SAFETY CONSIDERATIONS

SDU-2200Pro has been designed to meet the following voluntary and measurement standards:

- IEC 60601-1 Safety of Medical Electric Equipment
- UL60601-1:2003 Medical Electrical Equipment Part I : General Requirements for Safety
- AIUM NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment Revision 1 (AIUM 1998)
- AIUM NEMA UD3 Standard for Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUL 2 5 2006

Mr. Randal Walker National Service Manager Shimadzu Medical Systems 20101 South Vermont Ave. TORRANCE CA 90502-1328

Re: K061637

Trade Name: Diagnostic Ultrasound System SDU-2200Pro, System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: March 17, 2006 Received: June 13, 2006

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Diagnostic Ultrasound System SDU-2200Pro, System, as described in your premarket notification:



Transducer Model Number

<u>L040-075U</u>	<u>VA13R-050U</u>	<u>UB10R-065U</u>
<u>L040-120U</u>	VA20R-035U	EC11R-055U
L040-120HU	VA40R-035U	S011-050U
<u>L070-075U</u>	<u>VA40R-035HU</u>	<u>S017-035U</u>
<u>L072-050U</u>	<u>VA57R-0375WU</u>	<u>S020-025U</u>
<u>VA11R-055U</u>	<u>VA57R-0375HU</u>	
VA13R-035U	<u>TV11R-055U</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

Vancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

Ultrasound Device Indications Statement

Page 1 of 20.

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	Λ	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	ļ
Intra-operative (Specify)									·		
Intra-operative Neurological											
Pediatric		Ţ-	l								<u> </u>
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic								<u> </u>			
Cardiac		N	N	N		N	N	N	N	N	<u> </u>
Transesophageal				Ì							ļ
Transrectal		N	N	N		N	N_	N	N	N	<u> </u>
Transvaginal		N	N	N		N	N	N	N	N	
Transurethral			İ							<u> </u>	ļ
Intravascular								<u> </u>		<u> </u>	<u> </u>
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic										<u> </u>	
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	N		N	N	N	N	N	
Other (Specify)	1	1									_

Other Indications	or Modes:	
* Thyroid, Testicl	es, Breast	
** B/M, B/PWD,	CFM(B)/PWD, CFM(B)/CFM(I	M)
	(PLEASE DO NOT WRITE BELOW THIS L	INE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, (Office of Device Evaluation (ODE)
Prescription Use(Per 21 CFR 801.109)	\	(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number 206/637

Ultrasound Device Indications Statement Page 2 of 20.

510(k) Number (if known): _

K061637

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L040-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation Other Combined Color Tissue Power Clinical Application CWD Color В М PWD (Amplitude) (Specify) (Specify) ** Harmoni Velocity Doppler Imaging Doppler c **Imaging** Ophthalmic Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ N N N N N Ν Ν Ν (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transure thralIntravascular Ν N Ν Ν N N Peripheral Vascular N N Laparoscopic N N N Ν Ν Musculo-skeletal N N N Conventional N N N N N N N N Musculo-skeletal Superficial

N= new indication; P= previously cleared by FDA; E= added under Appendix E Other Indications or Modes: * Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M) (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number 606/637 Prescription Use.

(Per 21 CFR 801,109)

Other (Specify)

Ultrasound Device Indications Statement Page <u>3</u> of <u>20</u>.

510(k) Number (if known): K06/63 7
Device Name: Diagnostic Ultrasound System SDU-2200Pro, L040-120U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation Clinical Application PWD CWD. Color Power Color Combined Tissue Other (Amplitude) Doppler Velocity (Specify) ** Harmonic (Specify) Doppler Imaging Imaging **Ophthalmic** Fetal Abdominal Intra-operative (Specify) Intra-operative Neurological Pediatric Small Organ Ν N N N N N N N (Specify) * Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular N N N Ν Ν N N N Laparoscopic Musculo-skeletal Ν N N N Ν N Ν N Conventional

Other Indications or Modes: * Thyroid, Testicles, Breast ** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)

N

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,

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Prescription Use (Per 21 CFR 801.109)

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N= new indication; P= previously cleared by FDA; E= added under Appendix E

Musculo-skeletal

Superficial Others (Specify) Ultrasound Device Indications Statement Page 4 of 20 .

510(k) Number (if known):

Device Name: Diagnostic Ultrasound

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mod	ie of Opera	ation				
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal											1
Intra-operative											
(Specify)											
Intra-operative											<u> </u>
Neurological	<u> </u>										1
Pediatric											1
Small Organ		N	N	И		N	N.T.	NI	2.7		
(Specify) *		IN	l N	N		N	N	N	N	N	
Neonatal											
Cephalic		L									
Adult Cephalic	1										1
Cardiac											1
Transesophageal											
Transrectal											
Transvaginal						,					
Transurethral										1	
Intravascular											1
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic										· · · · · · · · · · · · · · · · · · ·	1
Musculo-skeletal		N	N	N		N .	N	N	N	N-	1
Conventional					i						
Musculo-skeletal		N	N	N		N	N	N	N	N	1
Superficial	<u> </u>		<u> </u>			•					
Others (Specify)								_		1	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

* Thyroid, Testicles, Breast		
* B/M, B/PWD, CFM(B)/PWI), CFM(B)/CFM(M)	
(PLEASE DO NOT	WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NE	EEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)	

Prescription Use _ (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number K 66/p 37

Ultrasound Device Indications Statement Page 5 of 20.

510(k) Number (if known): K 06/637

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L070-075U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Claric Lands	Г.	T =	T			le of Oper		,			· · · · · · · · · · · · · · · · · · ·
Clinical Application	Λ	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) **	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	<u> </u>	1									
Fetal	1.						Ī				
Abdominal							1				
Intra-operative (Specify)		i						<u>_</u>			
Intra-operative Neurological											
Pediatric		Ī								i	
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal Cephalic						,					
Adult Cephalic											1
Cardiac							1		1		
Transesophageal											1
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic									-		
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial		N	N	И		N	N	N	N	N	
Others (Specify)				"					1		1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PWD, CFM(B)/CFM(M)	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH, Office of Device Evaluation (ODE)	

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number

Prescription Use (Per 21 CFR 801.109)

Ultrasound Device Indications Statement Page 6 of 20 .

510(k) Number (if known): K061637

Device Name: Diagnostic Ultrasound System SDU-2200Pro, L072-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

	7					le of Opera					
Clinical Application	1	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	<u> </u>	<u> </u>									<u> </u>
Fetal							i				
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric	l										1
Small Organ (Specify) *		N	N	N		N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac	1						Ì				1
Transesophageal							<u> </u>				
Transrectal											
Transvaginal											
Transurethral		1									
Intravascular											1
Peripheral Vascular		N	N	N		N	N	N	N	N	
Laparoscopic											
Musculo-skeletal Conventional		N	N	N		N	N	N	N	N	
Musculo-skeletal Superficial											
Others (Specify)											1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
* Thyroid, Testicles, Breast	
** B/M, B/PWD, CFM(B)/PV	VD, CFM(B)/CFM(M)
(PLEASE DO N	OT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)
/) Janoy C Diractor
Prescription Use	(Division Sign-Off)
(Per 21 CFR 801.109)	Division of Reproductive, Abdominal.

Division of Reproduction and Radiological Devices K061637

Ultrasound Device Indications Statement

Page _7_ of _20_ .

510(k) Number (if known): <u>K06163</u>7

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA11R-055U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) **	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											1
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	1
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N		N	N	N	N	N	<u> </u>
Small Organ (Specify) *											
Neonatal Cephalic		N	N	N		N	N	N	N	N	
Adult Cephalic		N	N	N		N	N	N	N	N	
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal											
Transrectal											
Transvaginal						,	1				1
Transurethral					- *						·
Intravascular											
Peripheral Vascular									<u> </u>		
Laparoscopic											 -
Musculo-skeletal				1				·· · · · · ·		· <u></u> -	<u> </u>
Conventional											
Musculo-skeletal Superficial											
Others (Specify)						-			<u> </u>		-

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)	
Concurrence of CDRH, Office of Device Evaluation (ODE)	
Concentrative of CDRM, Office by Device Evaluation (ODE)	

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices X06/037

Ultrasound Device Indications Statement Page <u>8</u> of <u>20</u>.

510(k) Number (if known): K061637

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA13R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	1	В	М	PWD	CWD	Calor Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) **	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	<u> </u>										
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric	1										
Small Organ (Specify) *											
Neonatal Cephalic								•			-
Adult Cephalic							1				 -
Cardiac		N	Ν	N		N	N	N	N	N	
Transesophageal											
Transrectal	1							_	 		 -
Transvaginal	1								 		
Transurethral									1		
Intravascular					"		-				
Peripheral Vascular				~~							
Laparoscopic						·					<u> </u>
Musculo-skeletal Conventional								., ,-			1
Musculo-skeletal Superficial											
Others (Specify)									 		

	Other Indications or Modes:
	** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)
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	Concurrence of CDRH, Office of Device Evaluation (ODE)
) Janey (10) ontor
	(Division Sign-Off)
Daniel Maritim	Division of Reproductive, Abdominal,
Prescription Use (Per 21 CFR 801.1	
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Ultrasound Device Indications Statement Page 9 of 20.

510(k) Number (if known):_

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA13R-050U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

ar i i i	1 .		T			le of Opera	,	,			
Clinical Application	Λ	В	М	PWD -	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	<u> </u>	<u> </u>					<u> </u>	į			
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric						· · · · · · · · · · · · · · · · · · ·	1				
Small Organ (Specify) *											
Neonatal						-					
Cephalic					į		1			-	
Adult Cephalic									1 -		
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal							1				
Transrectal											
Transvaginal				-							
Transurethral											
Intravascular							1				
Peripheral Vascular											1
Laparoscopic								-	<u> </u>	<u> </u>	
Musculo-skeletal											1
Conventional]	
Musculo-skeletal											
Superficial										<u></u>	
Others (Specify)						<u> </u>					

0	ther Indications or Modes:
*:	* B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)
	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use(Per 21 CFR 801.10	(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number K00437

Ultrasound Device Indications Statement Page 10 of 20.

510(k) Number (if known): 14 06 1637
Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA20R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	-										
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	1
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											1
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic	Ī										1
Cardiac		N	N	N		N	N	N	N	N	
Transesophageal					i	·	Ì				†
Transrectal							1				
Transvaginal											1
Transurethral									1		
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial					·						
Others (Specify)											

_	Other Indications or Modes	s:
	** B/M, B/PWD, CFM(B)	/PWD,CFM(B)/CFM(M)
		·
_	(PLEASE D	O NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
		Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use(Per 21 CFR 801.16)9)	(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number

Ultrasound Device Indications Statement	Page	11	of
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510(k) Number (if known): K06/637

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA40R-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

	_		Y			ie of Oper		, · · · · · · · · · · · · · · · · · · ·			
Clinical Application	Λ	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	1
Intra-operative (Specify)				-						-	
Intra-operative Neurological											
Pediatric											-
Small Organ (Specify) *											
Neonatal	<u> </u>			.,			<u> </u>		 		
Cephalic	1										
Adult Cephalic						-	İ				
Cardiac							İ				1
Transesophageal								-	T		
Transrectal									1 "		
Transvaginal											
Transurethral										•	
Intravascular								-			
Peripheral Vascular								"			
Laparoscopic							1				
Musculo-skeletal											
Conventional											
Musculo-skeletal Superficial											
Others (Specify)									 		

Other	Indications or Modes:
	M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)
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	Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use(Per 21 CFR 801.109)	(Division Sign-Off) Division of Reproductive, Abdominai, and Radiological Devices 510(k) Number 106/637

Ultrasound Device Indications Statement Page 12 of 20.

510(k) Number (if known): _

Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA40R-035HU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Calor Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N ·	N	N	
Intra-operative (Specify)											-
Intra-operative Neurological									,		
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	1		1								
Transesophageal											
Transrectal											
Transvaginal							<u> </u>				
Transurethral							1				
Intravascular					Ì						
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)	1		Ì				<u> </u>				İ

N= new indication; P= previously cleared by FDA; E= added under Appendix E

B/M, B/PWD	, CFM(B)/PW	D,CFM(B)/CF	M(M)	<u> </u>	
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Prescription Use Der 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal,

and Radiological Devices 10(k) Number 1661637

Ultrasound Device Indications Statement Page 13 of 20.

510(k) Number (if known): 16061637 Device Name: Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375WU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric				-					† · · - · · ·	i	
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac								<u> </u>	<u> </u>		Ì
Transesophageal							1		1		
Transrectal								· ·			1
Transvaginal											<u> </u>
Transurethral											1
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)											

** B/M, B/PWD, CFM(B)	VPWD CEM(B)/CEM(M)
Dira, Bit WD, CI M(B	IT WD,CTM(M)
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	(Division Sign-Off) Division of Reproductive, Abdominal,
ption Use	and Radiological Devices
CFR 801.109)	510(k) Number K061(a31

Ultrasound Device Indications Statement Page 14 of 20.

510(k) Number (if known): <u>K 061637</u>. Device Name: <u>Diagnostic Ultrasound System SDU-2200Pro, VA57R-0375HU</u>

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

					MOG	te of Opera	uon				
Clinical Application	Λ	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	<u> </u>		<u> </u>	<u> </u>							
Fetal		N	N	N		N	N	N	N	N	
Abdominal		N	N	N		N	N	N	N	N.	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric					İ		İ	Ì			
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic	1	 	 						-		
Cardiac	 		 -	<u> </u>			 	<u> </u>	-		
Transesophageal									 		
Transrectal	Î						† · · · · · · · · · · · · · · · · · · ·				
Transvaginal									1		
Transurethral									<u> </u>		
Intravascular							1	i	1	· · · ·	
Peripheral Vascular							ĺ				
Laparoscopic							İ		7-"		1
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)									<u> </u>	-	

Other Indicatio	ons or Modes:	
	D, CFM(B)/PWD,CF	M(B)/CFM(M)
	-	
	(PLEASE DO NOT WRIT	FE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
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Prescription Use (Per 21 CFR 801.109)		(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number (1987)

Ultrasound Device Indications Statement Page 15 of 20.

510(k) Number (if known):

Device Name: Diagnostic Ultrasound System SDU

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N		N	N	N	N	N	
Abdominal							1				1
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric										·	1
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											
Cardiac									 		
Transesophageal				-				·			<u> </u>
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	1
Transurethral											1
Intravascular				•						1	
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional									_		
Musculo-skeletal Superficial											
Others (Specify)							1	İ	 		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications of	or Modes:
** B/M, B/PWD,	CFM(B)/PWD,CFM(B)/CFM(M)
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Division of Reproductive, Abdominal.

and Radiological Device

Ultrasound Device Indications Statement

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510(k) Number (if known): 15061637.

Device Name: Diagnostic Ultrasound System SDU-2200Pro, UB10R-065U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	Λ	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Dappler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic	1		1								
Fetal		ļ	1				Ī				
Abdominal							1				
Intra-operative (Specify)						,					
Intra-operative Neurological										-	
Pediatric]			Ī			1
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic	 	\vdash					 				
Cardiac	İ						 		 	· · · · · · · · · · · · · · · · · · ·	
Transesophageal	<u> </u>										†
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal							1		1		
Transurethral	1								<u> </u>		· · · · · · · · · · · · · · · · · · ·
Intravascular											
Peripheral Vascular		_					 				+
Laparoscopic	-	-						1		1	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)									 		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

ther Indications or Modes: * B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM	1/1/1	······································
DIM, DIT WD, CTM(B)/FWD,CFM(B)/CFM	VI(IVI)	
		
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Division of Reproductive, Abdominational Radiological Devices

510(k) Number K & 1637

Ultrasound Device Indications Statement

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510(k) Number (if known): 1
1
06163
Device Name: Diagnostic Ultrasound System SDU-

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

			-		Mod	de of Oper	ation				
Clinical Application	1	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal		N	N	N	Γ	N	N	N	N	N	
Abdominal											
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic										- -	1
Cardiac											
Transesophageal											1
Transrectal		N	N	N		N	N	N	N	N	
Transvaginal		N	N	N		N	N	N	N	N	1
Transurethral											1
Intravascular									1		
Peripheral Vascular											1
Laparoscopic											
Musculo-skeletal											
Conventional		<u> </u>		<u> </u>				<u> </u>			
Musculo-skeletal			<u>Г</u> '	_ '					T		
Superficial	<u> </u>		<u> </u>	!					ļ <u></u>		
Others (Specify)	1	1 1	1	1 !			ļ į			İ	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:	
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/CFM(M)	
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Prescription Use (Per 21 CFR 801.109)

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and Radiological Devices
510(k) Number KNG1637

Ultrasound Device Indications Statement Page 18 of 20.

510(k) Number (if known): K 061637 Device Name: Diagnostic Ultrasound System SDU-

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	1	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											1
Fetal											† · · · · ·
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric		N	N	N	N	N	N	N	N	N	† ·
Small Organ (Specify) *											
Neonatal											
Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal							Ī				
Transrectal							<u> </u>				
Transvaginal											
Transurethral		[
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal											
Conventional								<u> </u>	<u> </u>		
Musculo-skeletal Superficial											T
Others (Specify)											1

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD
Harmonic Imaging
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Ultrasound Device Indications Statement

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510(k) Number (if known) : <u>< 06163</u>

Device Name: Diagnostic Ultrasound System SDU-2200Pro, S017-035U

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

Mode of Operation

Clinical Application	A	В	М	PWD	CWD	Color Doppl er	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal	1			N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic											
Adult Cephalic											1
Cardiac	<u> </u>	N	N	N	N	N	N	N	N	N	1
Transesophageal											
Transrectal		-									<u> </u>
Transvaginal											
Transurethral									1		1
Intravascular	-										
Peripheral Vascular		<u> </u>									1
Laparoscopic											
Musculo-skeletal											1
Conventional											
Musculo-skeletal Superficial											
Others (Specify)									T		

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD
Harmonic Imaging
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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, Division of Reproduction and Radiological Devices April 237

Ultrasound Device Indications Statement Page 20 of 20.

510(k) Number (if known): K0616 Device Name: Diagnostic Ultrasound System

Fill out one form for each ultrasound system or transducer.

Indications for use: Diagnostic ultrasound imaging or Doppler analysis of the human body as follows:

					Mod	le of Oper	ation				
Clinical Application	A	В	М	₽₩D	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)**	Tissue Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal				N		N	N			N	
Intra-operative (Specify)											
Intra-operative Neurological											
Pediatric											
Small Organ (Specify) *											
Neonatal Cephalic						-					
Adult Cephalic											
Cardiac		N	N	N	N	N	N	N	N	N	
Transesophageal											
Transrectal					ĺ						
Transvaginal					Î						
Transurethral											
Intravascular											
Peripheral Vascular		l									
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Others (Specify)			1								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Other Indications or Modes:
** B/M, B/PWD, CFM(B)/PWD,CFM(B)/PWD,CFM(B)/CFM(M),B/CWD,CFM(B)/CWD
Harmonic Imaging
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Prescription Use (Per 21 CFR 801.109)

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